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EXAMINER

DATLOW, P

12M2/0822

ART UNIT

PAPER NUMBER

5

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1202

DATE MAILED:

08/22/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 8/14/95 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892. 2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449. 4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.. 6.

Part II SUMMARY OF ACTION

1. Claims 13-28 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1-12 have been cancelled.

3. Claims 17-19, 21 are allowed.

4. Claims 13-16, 20, 22-28 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

1. Claims 13-14 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 13: The last listed Q group is incorrect since it has too many valences for the ring carbon atoms in the epoxide ring. ✓

2) Claim 14: The second listed R group is incorrect for having too many hydrogens on the carbon atom. ✓

3) Claim 25: At lines 2-3, the following language is indefinite and confusing: "same, a the 13

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the originally filed specification fails to support the presently claimed subject matter.

The original specification fails to provide written description or enablement support for the specific species identified in new claims 20 and 22. For claim 20, applicants point to Table II at pgs. 19-21 of the specification. However, note that the closest example 3 therein fails to provide for the beta orientations in the 6,7-dehydro group as claimed. ✓

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For the species of claim 22, applicants point to compound 31 at pg. 21 of the specification. However, note that this compound has a cyclopentyl R₁ group, not a cyclopropyl as claimed.

3. Claims 20, and 22-28 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. ✓

4. The amendment filed 8/14/95 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the Abstract, compounds (b) and (d) for the reasons noted in the above rejection under Section 112, 1st paragraph. ✓

Applicant is required to cancel the new matter in the response to this Office action.

5. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim(s) 13-16 and 23-28 are rejected under 35 U.S.C. § 103 as being unpatentable over The Merck Index in view of Grimminger et al. The primary reference(s) of The Merck Index teach(es) the compounds Buscopan® and Atrovent® at pgs. 242 and 802, as compounds 1588 and 4960. These compounds are taught to be useful as antispasmodics and bronchodilator/antiarrhythmics, respectively. The claims differ in that the instant compounds are structurally different in acid component of the ester. The prior art compounds have a aryl, hydroxyalkyl grouping in the acid component, whereas the instant compounds have a diaryl, hydroxy grouping, where one aryl group is thienyl.

The secondary reference(s) teach(es) that many of the instantly claimed diaryl, hydroxy groupings in the acid component is conventional in this art of spasmolytic (antispasmodic) tropanol compounds. See Grimminger et al, formula (I) at Col. 2, lines 55+, and the R₁ and R₂ definitions at Col. 4, lines 16+; Note thienyl and cyclic groups are mentioned. Therefore, in view of the teaching(s) of the secondary reference(s), one having ordinary skill in the art would have been motivated to modify the primary reference(s) by replacing the acid component in the Merck Index compounds with the diaryl, hydroxy grouping, where one aryl group is thienyl, to

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obtain the instant compounds. Such modification would have been obvious because the secondary reference teaches that such an acid component is conventional in this art.

Applicants comments in the Information Disclosure Statement filed 8/14/95 are noted, but are not persuasive. Applicants not different activities for the instant compounds versus the compounds noted from the Merck Index. However, no comparative evidence of unexpectedly superior results has been presented to support applicants' statements.

6. Claims 17-19 and 21 are allowed. The prior art of record does not teach or suggest the substitution patterns on the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip I. Datlow whose telephone number is (703) 308-4710. The examiner can normally be reached on weekdays from 9:00 am to 5:30 pm.

The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Philip I. Datlow
Primary Examiner
Group 1200-Art Unit 1202